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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,462	05/26/2000	Stephen Fox Heinemann	SALK1590-3	2034

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/580,462

Applicant(s)  
Heinemann et al.

Examiner  
John Ulm

Art Unit  
1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 19, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11, 12, and 14-33 is/are pending in the application.
- 4a) Of the above, claim(s) 28-30 and 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 is/are allowed.
- 6) ☒ Claim(s) 5, 6, 8, 9, 11, 12, 14-27, 31, and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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1) Claims 5 to 9, 11, 12 and 14 to 33 are pending in the instant application. Claims 5 to 9, 11, 12, 15 and 16 have been amended and claims 18 to 33 have been added as requested by Applicant in Paper Number 8, filed 19 April of 2002.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) The figures in the instant application clearly fail to meet the requirements of 37 C.F.R. § 1.84(U)(1), for those reasons of record in section 2 of Paper Number 6. **Correction is required.**

5) Claim 7 would be allowable if it complied with 37 C.F.R. § 1.84(U)(1).

6) Newly submitted claims 28 to 30 and 33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 28 to 30 are drawn to nucleic acid probes, classified in class 536, subclass 24.31, and claim 33 is drawn to a non-coding nucleic acid classified in class 536, subclass 24.1, each of which is a chemically different compound from the originally elected invention of a nucleic acid encoding a polypeptide, classified in class 536, subclass 23.5. Distinctness is shown by the fact that each of the different nucleic acids, as claimed, can be made and used without the others.

Since applicant has received an action on the merits for the originally presented invention, the invention has been constructively elected by original presentation for prosecution on the

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merits. Accordingly, claims 28 to 30 and 33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

7) Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for those reasons of record in section 5 of Paper Number 6.

8) Claims 5, 8, 9, 11, 12 and 14 to 27, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for those reasons of record as applied to claims 5, 8, 9 and 11 to 17 in section 6 of Paper Number 6. The instant specification provides an adequate written description of an isolated nucleic acid encoding the amino acid sequence presented in Figure 7B of the instant application, and nothing else. Applicant urges that the instant specification describes a plurality of properties which Applicant expects to be common to all proteins encompassed by the term “neuronal nicotinic acetylcholine receptor beta2 subunit”. Such arguments were equally applicable to the term “mammalian insulin” in the decision of *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997). However, the instant claims are not drawn to a “neuronal nicotinic acetylcholine receptor beta2 subunit”, they are drawn to an isolated nucleic acid, and the only isolated nucleic acid encoding a “neuronal nicotinic acetylcholine receptor beta2 subunit” which is described in the instant specification is presented in Figure 7. No other nucleic acid meeting the limitation of the

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instant claims is described in the instant specification. The court has repeatedly held that the description of a nucleic acid molecule solely by the functions of a protein one requires it to encode is nothing more than a wish to know the identity of compounds possessing the recited functions (*Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016 (Fed. Cir. 1991)).

Further, the limitation "having greater than about 68% sequence homology" in claim 11 does not appear to be supported by the specification as filed. This limitation is new matter.

9) Claims 5, 6, 8, 9, 11, 12, 14, 16 to 27, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9.1) Claims 5, 6, 12, 14 to 24, 26, 27, 31 and 32 are vague and indefinite because there is no antecedent basis for "the sense strand". First, a DNA molecule does not have to be double stranded. Second, a double stranded DNA molecule can encode proteins on both strands. Therefore, the recitation of "[a] substantially pure DNA" does not provide an adequate basis for "the sense strand".

9.2) Claims 5, 6, 8, 9, 11, 12, 14 to 27, 31 and 32 are vague and indefinite in reference to the term "beta2" for those reasons of record as applied to claims 5 to 9, 11, 12, 14 to 27 in section 7 of Paper Number 6. The properties identified by Applicant in traversal of this rejection are not identified in the instant specification as exclusive to a protein encompassed by the term "beta2". The features described therein appear to be common to all neuronal nicotinic acetylcholine receptor beta subunits. Because the instant specification does not identify that

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property or combination of properties **which is unique to** and, therefore, definitive of a “beta2” subunit an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

9.3) Claims 15, 25 to 27 are vague and indefinite because the limitation “under stringent conditions” is conditional and **no single specific set of conditions which define this limitation** are recited in either the claims or the specification.

9.5) Claims 22 and 24 are vague and indefinite because it is unclear which “neuronal nicotinic acetylcholine receptor alpha subunits” the claim is referring to. The limitation “has approximately 50% sequence identity” requires a specific point of reference and none is given. One of ordinary skill would assume that there are thousands of different “neuronal nicotinic acetylcholine receptor alpha subunits” in the animal kingdom and the claims do not identify which of these different subunits are to be considered in calculating a “sequence identity” value for a given molecule.

10) Applicant's arguments filed 19 April of 2002 have been fully considered but they are not persuasive.

11) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800**